SCHEMA – PROTOCOL T

TITLE: A dose-escalation trial of drug X

DESIGN: Open-label, dose-escalating, safety and activity trial of drug X for the treatment of HIV infection.

POPULATION: Appropriate population (HIV-infected, HIV-uninfected, pediatrics, women, pregnant women, etc.)

DURATION: 90 days

PRIMARY OBJECTIVE(S): To assess safety and tolerability of the drug
To obtain preliminary efficacy information

SECONDARY OBJECTIVES: To establish a maximally tolerated dose
To explore the virologic and immunologic activity of the drug

SCHEDULE OF EVENTS FOR THE FIRST TWELVE MONTHS – PROTOCOL T

Evaluations	Screening									
		0	3	7	14	21	28	60	90	d/c
		Treat with Drug X days 1-14								
Determine HIV status	X									
Medical History and Physical exam	X	X		X		X	X	X	X	X
Hematology	X	X		X		X	X	X	X	X
Chemistry Panel	X	X	X	X	X	X	X	X	X	X
Pregnancy test	X	X	X		X		X	X	X	X
Urinalysis	X	X								
Specimen storage: plasma		X		X	X				X	X
Specimen storage: PBMC's		X		X	X				X	X
Medication adherence assessment; distribution/collection of medication log		X		X	X					X
PK Sampling (36 hours intensive admissions)		X		X	X					
24 Hour Urine Collection		X		X	X					
Electrocardiogram (ECG)	X	X		X	X		X			
HIV-1 RNA	X	X		X	X		X		X	X
CD4+ and CD8+ cell counts	X	X		X	X		X		X	X